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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/700,187 | 11/13/2000 | Yukiko Sasaki | 275352 | 2634 |

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| EXAMINER | |
|---|---|
| HELMER, GEORGIA L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

DATE MAILED: 05/27/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/700,187 | SASAKI ET AL. | |
| | Examiner | Art Unit | |
| | Georgia L. Helmer | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. The office acknowledges receipt of Applicant's Amendment, Paper No. 11, dated 25 February 2003, as well as the certified copy of Japanese application No. 066551/1999, the Japanese priority document.

### *Status of the Claims*

2. Applicant has amended claims 1-8 and 11-13, and added new claims 14 and 15. Claims 1-15 are pending, and are examined in the instant office action.

3. All rejections not addressed below have been withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### Invention Disclosure Statement

5. The Office acknowledges receipt of Applicant's Information Disclosure Statement (PTO-1449), filed 13 November 2000. A signed copy of Applicant's Information Disclosure Statement is enclosed.

### *Claim Rejections - 35 USC § 101*

6. Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A progeny of the plant and a part of the progeny, are produced by sexually crossing and are subject of Mendelian segregation. Since these plants have not been subjected to selection for the heterologous DNA, wild-type progeny are included and thus the claim reads on products of nature.

***Claim Rejections - 35 USC § 112-second***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent that this is a new rejection, it is necessitated by Applicant's amendment.

- Re "gene" in claims 1 and all claims dependent thereon, the previous Office Action suggested interpreting "gene" to mean "a DNA coding sequence". The Office takes the definition of "gene" to be a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. In order to be consistent with Office practice, and for clarification, it is

suggested that all recitations of "gene" be amended to recite "DNA coding sequence". Any inconvenience to Applicant is regretted.

- "expression of a gene placed downstream of said DNA fragment and a promoter operably linked to said gene" need to be clarified re whether "placed downstream " refers to just the DNA fragment or to both the DNA fragment and the promoter.
- "the presence of light" is unclear because it lacks disclosure of how much light, how long an exposure, and what kind of light. Does "presence of light" encompass everything except complete darkness?

Applicant traverses, stating primarily saying the amended claims use comparative terms to define the repressive effect. Applicant's traversal has been considered and is unpersuasive because using comparative language solves one of the problems with "the presence of light", but the problem not addressed is: "the presence of light" is unclear because it lacks disclosure of how much light, how long an exposure, and what kind of light. Does "presence of light" encompass everything except complete darkness?

In claim 2, "cis-element" is unclear. What does this mean? What are the components of the "cis-element"?

In claim 3, "a constitutive promoter in the sequence of SEQ ID NO: 3" is unclear because this implies the presence of an additional promoter.

In claim 4, "in the upstream is unclear" because the upstream of what is not specified.

Claims 11, 12, 13, are improper multiply dependent claims.

In Claim 13, what does "organ part" mean?

Correction/clarification is required.

9. ***Claim Rejections - 35 USC § 112-1st, written description***

Claims 2, 5, and 7-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to " nucleotide sequence obtained by deletion, substitution and/ or addition of one or more bases in SEQ ID NO: 2, other than SEQ ID NO: 1". However Applicant has not given a representative number of additions, substitutions and/or deletions which have the desired function. encompass many changes, from single nucleotides to very large sequences. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

***Claim Rejections - 35 USC § 112-1st, new matter***

10. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejected subject matter is "a promoter operatively linked to said gene". Applicant is invited to point out the page and line number in the specification where "a promoter operatively linked to said gene" can be found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

***Claim Rejections - 35 USC § 112-1st, enablement***

11. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The claims are drawn to an isolated DNA fragment containing the sequence of SEQ ID NO: 1 as a core sequence , whereby expression of a gene placed downstream of said DNA fragment and a promoter operably linked to said gene is repressed in the presence of light compared with expression in the dark. A DNA sequence search of SEQ ID NO: 1 produced 45 hits out of the first 45 results, all with 100% match. Most of these matched sequences are mammalian DNA sequences, and show no expression or repression function. Therefore, it is highly unpredictable that any DNA fragment containing SEQ ID NO: 1 would function to repress expression. For example, an 88 bp *Saccharomyces paradoxus* fragment of a genomic clone (AZ925237, Cliften et. al., 2001), a *Mus musculus* genomic clone 128 bp fragment (AZ289196, Zhao et. al., 2000), and a human clone (AI610647, Adam, et. al.,1998) show no evidence of the claimed activity. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Even if Applicant were enabled, this would be enabled only to the extent of claims limited to recitation of a "promoter operatively linked" to said gene, and where the limitation "nucleotide sequence obtained by deletion, substitution and/

or addition of one or more bases in SEQ ID NO: 2, other than SEQ ID NO: 1" does not occur.

RE a "promoter operatively linked" to said gene: It is well known in the art that in order for expression to occur, a promoter and the coding sequence of interest must be operatively linked. Neither Applicant nor the prior art teaches how to allow a promoter to function to promote expression, other than by an operable linkable between the two.

RE "a nucleotide sequence obtained by deletion, substitution and/ or addition of one or more bases in SEQ ID NO: 2, other than SEQ ID NO: 1": Additions, substitutions and/or deletions encompass many changes, from single nucleotides to very large sequences. No guidance is given other than that the core sequence of SEQ ID NO: 1 be retained in the final sequence. It is known in the art that many factors effect gene expression, including access to RNA polymerase and associated transcription factors (Jackson, 1997, Chromatin domains and nuclear compartments: establishing sites of gene expression in eukaryotic nuclei. Mol. Biol. Rep. 24, 209-220), as well as matrix attachment regions (Allen, et. al. Use of matrix attachment regions (MARs) to minimize transgene silencing, 2000, Plant Molecular Biology 43: 361-376). It is unpredictable that any single one of these polynucleotide sequences would function in the same way as SEQ ID NO: 2. In fact most would be nonfunctional. Without further guidance, one of skill in the art would be required to do many experiments involving a myriad of combinations. This would impose a burden on the skilled artisan, without a reasonable expectation of success.

In view of the breadth of the claims (any gene, any DNA fragment, any DNA fragment containing the sequence of SEQ ID NO: 1 as a core sequence, any nucleotide sequence obtained by deletion, substitution and/ or addition of one or more bases in SEQ ID NO: 2, other than SEQ ID NO: 1, any plant and any promoter) and the lack of guidance in the specification, undue experimentation would be required to enable the invention as commensurate in scope with the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

***Claim Rejections - 35 USC § 102***

12. Claims 1, 2, and 4-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Strasberg, et. al., ( Accession AA579315, NCI, Tumor index registry, 12 September 1997, see result 7, EST database search, attached); Okubo et. al, (Accession D25785, 30 November 1995, see result 6, EST database search, attached) and Adams, et. al., (Accession AQ009485, 27 June 1998, see result 9, EST database search, attached).

Strasberg et. al., Okubo et al, and Adams, et al, recite SEQ ID No : 1 and thus expression of a polynucleotide sequence placed downstream of SEQ ID NO: 1 and a promoter operably linked to said polynucleotide sequence would inherently be repressed in the presence of light.

NO: 1 and a promoter operably linked to said polynucleotide sequence would inherently be repressed in the presence of light.

Accordingly, Strasberg et. al., Okubo et al, and Adams anticipate the claimed invention.

***REMARKS***

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer
Patent Examiner
Art Unit 1638
May 19, 2003

PHUONG T. BUI
PRIMARY EXAMINER